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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,765	02/12/2002	Gurdip S. Brar	38-21(15532)	7872

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MONSANTO COMPANY
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EXAMINER	
HELMER, GEORGIA L	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/683,765	BRAR ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12 February 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-29 are pending, are examined in the instant action.

Information Disclosure Statement

2. Applicant's IDS filed 16 September 2002, is acknowledged and a signed copy included herewith.

Priority

3. Applicant's ADS is inconsistent with the first line of the specification, in that no priority is listed on the ADS. Applicant is required to file a supplemental ADS.

Claim Rejections - 35 USC § 112 Enablement

4. Following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1-29 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing transformed sunflower cotyledons comprising, a/ obtaining a cotyledon from germinated sunflower seedling, b/ cocultivating Agrobacterium bearing a heterologous DNA sequence together with the cotyledon in an infiltration media comprising benzylaminopurine, sucrose, acetosyringone and Stilwet surfactant, for 48 hours, in the light, c/ culturing the Agrobacterium and cotyledon in a high osmotic pressure medium comprising sucrose, benzylaminopurine for 7 days in light,

d/ culturing the cotyledons on a series of selection medium comprising sucrose, benzylaminopurine, cefotaxime + carbenicillin, and the selection agent glyphosate, to form transgenic shoots, which were then e/ cultured on shoot media comprising sucrose, cefotaxime + carbenicillin + gibberillic acid, followed by f/ culture on shoot development media comprising sucrose, cefotaxime + carbenicillin and GA3 in high light conditions for about 10 days, as taught in the specification on pages 26-30, does not reasonably provide enablement for the broad scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

The breadth of the claims: The claims are drawn to a method of producing transformed sunflower cotyledons by a method of obtaining a cotyledon of germinated sunflower seedling, contacting the cotyledon with Agrobacterium , culturing Agrobacterium contacted cotyledon with a first media to produced transformed sunflower cotyledon tissue where the first media has high osmotic pressure, including shoot growth from transformed sunflower cotyledons tissue in second media which has a low osmotic pressure, and selecting transformed sunflower cotyledon tissue. The claims are further limited to wherein the high osmotic pressure is between 200 mOsm to about 750 mOsm, where the first media contains a carbohydrate, where the carbohydrate is

glucose, sucrose, mannitol, fructose, maltose, mannose, or xylose; where the carbohydrate concentration is about 5% to 30%; where the fist media contains 6-benzylaminopurine; where the cotyledon is processed along the axis between the root and shoot prior to contacting the cotyledon with the culture of Agrobacterium ; where the cotyledon is incubated at a temperature between zero degrees C and 10 degrees C prior to contacting the cotyledon with the Agrobacterium; where the cotyledon is cotyledon is contacted with the culture of Agrobacterium in an infiltration media comprising one or more cytokinins and one or more carbohydrate; where the carbohydrate is sucrose; where the concentration of carbohydrate is the infiltration media is less than about 5%; where the cytokinin is less than about 0.5 microgram/ml; where the transformed sunflower cotyledon tissue is incubated in a selection media containing a selection agent; where the selection agent is glyphosate, paromomycin, G418 or kanamycin; where the glyphosate is about 0 mM to about 0.5 mM; where the transformed sunflower cotyledon tissue is sequentially transferred to a first, second, and third selection media. Claims are also drawn to the method further comprising the step of culturing the transformed sunflower cotyledon tissue to produce transgenic shoots; and further comprising a step of culturing the transgenic shoots to produce a transgenic sunflower plant; further comprising the step of grown the transgenic sunflower plant to produce transgenic sunflower seeds. Further claims are drawn to the method where the Agrobacterium comprises a recombinant nucleic acid vector; which further comprises a selectable marker.

The state of the art and the unpredictability thereof: Plant transformation is unpredictable. According to Hansen, "[P]lant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one", (Hansen et. al., 1999, Trends in plant Science, Vol 4, pages 226-231, see page 230). Moreover, sunflower is a plant recalcitrant to transformation. Applicant says that "sunflower tissues ..have been refractory of standard transformation and regeneration protocols" (specification ¶ 0059). Furthermore, Laparra, et. al. (IDS), discussing his evaluation of three gene transfer methods of foreign genes in sunflower, observed that stable transformation was only observed after Agrobacterium transformation, and that "the infection efficiency [with Agrobacterium] was critically dependent on the coculture conditions".

Guidance and the presence of working examples: Applicant teaches a method of producing transformed sunflower cotyledons comprising, a/ obtaining a cotyledon from germinated sunflower seedling, (specification p.25), b/ cocultivating Agrobacterium bearing a heterologous DNA sequence together with the cotyledon in an infiltration media comprising benzylaminopurine, sucrose, acetosyringone and Stilwet surfactant, for 48 hours, in the light, c/ culturing the Agrobacterium and cotyledon in a high osmotic pressure medium comprising sucrose, benzylaminopurine for 7 days in light,

d/ culturing the cotyledons on a series of selection medium comprising sucrose, benzylaminopurine, cefotaxime + carbenicillin, and the selection agent glyphosate, to form transgenic shoots, which were then e/ cultured on shoot media comprising sucrose, cefotaxime + carbenicillin + gibberillic acid, followed by f/ culture on shoot development media comprising sucrose, cefotaxime + carbenicillin and GA3 in high light conditions for about 10 days, as taught in the specification on pages 26-30. Applicant describes the production of transformed sunflower cotyledon, transformed sunflowers, and seeds of transformed sunflowers.

Experimentation required: Undue experimentation would be required to determine which culture conditions to use for cocultivating the cotyledon with the Agrobacterium (what media, containing which carbohydrates, if any, and at what concentration, containing which plant growth regulators, if any, and it yes, then at what concentration, and what does "high osmotic pressure" mean and what is high relative to, also, are Agrobacterium vir inducers added to this media, if yes, which one(s) at which concentration, also is a surfactant added, which one, and at which concentration) as well as the time duration for cocultivation, and what are the light/dark conditions for cocultivation; as well as what are the conditions for inducing shoot growth from the cotyledon (what media, containing which carbohydrates, if any, and at what concentration, containing which plant growth regulators, if any, and it yes, then at what concentration, and what does "low osmotic pressure" mean and what is low relative to) and what is the time duration for this treatment, as well as what are the light/dark conditions. Having done

these matrices of experiments, the selection condition would have to be determined—what selective agent, at what concentration, for what length of time, in what light/dark conditions, and are there more than one round of selections. If the Agrobacterium bears heterologous DNA, what is the payload here—what genes, bearing which coding sequences, which regulatory sequences and are they constitutive or otherwise regulated re tissue specificity or exogenous inducers. Applicant must provide sufficient guidance to address these issues. Without such guidance the experimentation required would not be routine, but would be undue. This would impose a burden on the skilled artesian, without a reasonable expectation of success.

In view of the breadth of the claims (all Agrobacterium. all culture media, all growth conditions, all carbohydrates, all plant hormone sand all selectable markers), the nature of the invention, the unpredictability of the art, the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Remarks

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
October 1, 2004

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